

REMARKS/ARGUMENTS**Summary of Amendments, status of claims**

Claims 1 and 16 are amended by the addition of limitations.

Claims 2, 3, and 17 are amended by the deletion of limitations.

- 5 Claims 2-3, 8-12, and 20 are amended for antecedent basis purposes. Also, claim 20 has been made dependent on claim 1, and rewritten.

Claims 15, 18 and 19 are canceled.

New claim 24, based on canceled claim 18, is added.

Claims 1-3, 8-12, 16-17, 20 and 24 are pending.

10 **Support**

Claim 1 has been amended to recite "noninvasive cancer screening method".

The recitation is supported by page 4, line 9 which reads: "A first embodiment of the invention provides a non-invasive cancer screening method."

- 15 Claim 1 has been amended to recite "obtaining a saliva sample from a human not diagnosed with cancer". The recitation is fairly supported by page 4, lines 9-11, which reads: "A saliva specimen is obtained from the normal population not diagnosed for cancer to be screened and is formed into a saliva sample."

Claim 1 has been amended to recite "assaying the assay sample by simple ELISA test to determine whether an immunological reaction has occurred in the assay sample, wherein ELISA test results higher than a predetermined value are indicative of a positive screening test for cancer." The recitation is fairly supported by page 6, lines 11-15, which reads: "Preferably, the step of
5 determining is carried out by simple ELISA test to obtain ELISA test results which are most preferably either titer or binding affinity. Positive results from either of these tests are indicative of the occurrence of an immunological reaction in the assay sample, and obtaining ELISA test results above a predetermined value are indicative of a screening test positive for cancer."

Claim 16 has been amended to recite: "providing a mixture of proteomic cancer markers obtained
10 from breast, liver, colon, and ovarian cancers." The limitation is fairly supported by page 9, line 21, which reads: "*Mix PCM consisted of mixture of PCMs for breast, colon, liver and ovary".

Claim 16 has been amended to recite: "said mixture containing proteomic cancer markers identified and markers not yet identified". This limitation is fairly supported by page 7, lines 25-
15 26, which reads: "Each type of cancer cell has it's own identified and not yet identified cancer markers."

Claim 16 has been amended to recite: "forming a reagent from said polyclonal antibodies". The limitation is fairly supported by page 5, lines 17-19, which reads: "The blood containing the polyclonal antibodies is collected from the animals and further separated into a serum containing the polyclonal antibodies from the blood. The reagent is formed from the serum".

20 The limitations in claim 16 of "human not diagnosed with cancer" and "assaying by simple ELISA" are supported as for claim 1.

The limitation in claim 16 of "wherein ELISA titer test results of greater than 1,000 are indicative of a positive screening test for cancer" is fairly supported at page 10, lines 11-12, which reads as follows: "At this stage the titers above 1:1000 were considered as tentatively positive for early

diagnosis of cancer.”

5 The limitation in claim 20 of “bringing each portion of the second saliva sample together with a reagent produced by providing a mixture of proteomic cancer markers identified and markers not yet identified from a single type of cancer cells, forming polyclonal antibodies against the mixture, and forming the reagent from the polyclonal antibodies, to form an assay sample” is fairly supported by page 6, lines 18-23, which reads as follows: “A second saliva sample from the patient is divided into a plurality of portions, and these portions are brought together with a plurality of second reagents, a single reagent being brought together with each portion. Each second reagent contains a separate slate of antibodies made against proteomic cancer markers from different types of cancer cells, one type of cancer cells being used to form each slate of antibodies. A plurality of second assay samples is thus formed” in view of page 7, lines 25-28, which states: “Each type of cancer cell has its own identified and not yet identified cancer markers. For example, the identified oncogenes for breast cancer are erb and CA-15-3, and there may be more which are yet not identified. Therefore, each type of cancer cell most likely has array of cancer oncogene product, and releases multiple PCMs.”

20 The limitation in claim 20 of “conducting a simple ELISA test on the assay sample, wherein an ELISA test result higher than a predetermined value is indicative of a positive screening test for proteomic markers of said cancer cell type” is fairly supported by page 6, lines 11-15, which reads as follows: “the step of determining is carried out by simple ELISA test to obtain ELISA test results which are most preferably either titer or binding affinity. Positive results from either of these tests are indicative of the occurrence of an immunological reaction in the assay sample, and obtaining ELISA test results above a predetermined value are indicative of a screening test positive for cancer.”

Discussion

25 During the interview, the Examiner indicated that further amendments appeared desirable for greater clarity. The undersigned agreed to submit such amendments.

Conclusion


In view of the foregoing, reconsideration and withdrawal of all grounds of rejection and early notice of allowance is respectfully solicited.

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